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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/688,089 10/16/00 HANSEN

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EXAMINER

HUFF, S

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/26/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Applicati n No.

09/688,089

Applicant(s)

HANSEN, HANS J.

Examiner

Sheela J Huff

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1642

-- The MAILING DATE of this communicati n appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 30-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

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DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6132718. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of claims is the scope--the claims of the patent require an additional step of a vaccine comprising an anti-ID.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eshhar et al PNAS vol. 90 p. 720 (1/1993), WO 92/15322, Wagner et al, Biotechnology Therapeutics vol. 3 p. 81 (1992) and applicant's admission on page 22(lines 10-24) of the specification as applied to claims 15-17 and 30-31 above, and further in view of Hansen et al, Cancer vol. 71 p. 2478 (1993).

Eshhar et al disclose the construction and use of chimeric genes comprised of a single-chain Fv domain of an antibody linked to the T cell receptor (TCR) or CD3, which is the principal triggering receptor complex of T cells(p. 720-second column-second full paragraph). The mechanism of action of the gene, includes being expressed in T cells, and when encountering the antigen, the complex emits signals for T cell activation, which results in the secretion of lymphokines and target cell lysis. (p. 720-second column-top). This reference also discloses the use of such chimeric genes in adoptive immunotherapy(p. 720-first column, first paragraph after the abstract).

The only difference between the instant invention and the reference is a specific showing that the chimeric gene can use used in adoptive immunotherapy, a specific showing that the immunoglobulin used can recognize a TAA or a disease caused by an infectious agent and the use of cytokines and/or the administration of an anti-ID and the specific use of CEA.

The WO shows that such chimeric genes can be used in adoptive immunotherapies where the disease is either a tumor or an infectious state(p. 29 and p. 1).

On page 22 of the specification, applicant admits that it is routine in the art to administer cytokines in immunotherapy to further the immune response.

Wagner et al teach the approach of tumor immunotherapy by the activation of the idiotypic network. This approach uses both Ab1 and Ab2 antibodies and produce an Ab2 β which mimics the TAA. Thus, this reference not only shows that antibodies directed against TAA are known but also that the induction of the idiotypic network results in tumor therapy. See entire reference.

Hansen et al shows that CEA is a TAA (see entire reference). CEA is a well known tumor associated antigen that is expressed most adenocarcinomas of entodermally-derived digestive system epithelia, breast tumor cells and non-small cell lung cancer cells (see pages 1-2 of specification).

In view of the disclosure in Eshhar et al to use the chimeric genes in adoptive immunotherapy and in view of the disclosure of the WO which shows that such chimeric genes can be used in diseases caused by either tumors or infectious agents, it would

have been obvious to one of ordinary skill in the art at the time of the invention to use the chimeric genes of Eshhar et al in adoptive immunotherapy to treat tumors and infectious diseases. In view of the additional disclosure of Eshhar et al that many adoptive immunotherapy techniques lack specificity, it also would have been obvious to have the immunoglobulin encoding region of the chimeric gene encode an antibody that was specific for specific antigens on the surface of cells (ie TAA's). As demonstrated in Wagner et al, such antibodies are known in the art. Since it is within the purview of one skilled in the art to combine two known treatment techniques, it also would have been obvious to induce the idiotypic network (as described by Wagner et al) in combination with adoptive immunotherapy technique of Eshhar et al. In view of the well known knowledge that CEA is well known TAA, the use of CEA in the adoptive immunotherapy would have also been obvious to one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on M,Th 5:30 am-2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sheela J Huff
Primary Examiner
Art Unit 1642

sjh
October 22, 2001